Pharmacy NewsCapsule

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Standards for Drug Packaging

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The United States Pharmacopeia (USP) sets various standards for drug packaging, storage, expiration dating, labeling, and other drug standards that pharmacists, drug manufacturers, wholesalers, hospitals, and others must follow to ensure that medications patients receive provide the benefit they are intended to provide. Recently, in the first supplement to *The United States Pharmacopeia, 24th Rev. and The National Formulary, 19th Ed. (USP24/NF19)* various significant updates have been implemented.

There is one change in particular that is significant. Pharmacists who repackage medications into single unit or unit-dose containers are now allowed to use a beyond-use date of 1 year or the manufacturer's expiration date, which ever is less. The exception to this rule is medications that have other stability data to the contrary (e.g. liquid antibiotics that are reconstituted have much shorter beyond-use dates). Prior to this change, beyond-use dating was limited to 6 months or 25% of the remaining manufacturer's expiration date which ever was less.

Some of you may ask "What is a Beyond-Use Date?" The beyond-use date is the date that defines how long a prescription drug can be used after it has been

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Advancing Parkinson's Disease and Medication Issues

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This article will address complications that occur as Parkinson's disease progresses. In addition, some medications used to treat Parkinson's will be discussed.

Parkinson's disease causes a decrease in dopamine. It is for those reasons levodopa (a drug that forms dopamine) is usually used to replace lost dopamine. As Parkinson's disease progresses, those individuals on levodopa (Sinemet®) usually experience increased motor complications. More specifically these individuals will experience a "wearing-off" phenomena and dyskinesias. "Wearing-off" is basically a condition where levodopa treatment is no longer is as effective as it was in the past. Affected individuals tend to experience fluctuations in motor performance to the extent that, in some dramatic cases, they may be ambulatory at one point and then immobile at another part of the day.

Dyskinesias on the other hand, are involuntary, rapidly flowing, and nonstereotyped movements of the limbs, trunk, and/or head. Limbs that are affected by dyskinesias will appear to be in constant motion. In those individuals on levodopa, presentation of dyskinesias is usually a sign that there is too much levodopa being used. Usually a decrease in the amount of levodopa being administered will eliminate the dyskinesia. The unfortunate result of a decrease in the levodopa, however is a concomitant worsening of the parkinsonism. It's a delicate balancing act.

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New Drugs

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Brand Name	Generic Name	Use
Glucovance	Glyburide/metformin combination	Oral tablets for improving glycemic control in type 2 diabetes
Quixin	Levofloxacin	Eye drop for treatment of bacterial conjunctivitis.
Rescula	Unoprostone	Eye drop for glaucoma.
Colazal	Balsalazide	Oral capsule for mild to moderate ulcerative colitis.
Abreva	Docosanol	Cream for treating recurrent oral-facial herpes simplex infections.

Med Error Corner

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Sometimes the biggest question health care workers have is "Where or how do I report a medication error?" First, internal reporting within the facility is essential. Medication error reporting needs to involve the attending physician, nurses, pharmacists and others involved in the health care team. Most facilities know this and have policies and procedures in place.

What many facilities may be unaware of are various voluntary programs available through which to report errors. These programs are a critical link to assisting others in avoiding similar errors. The current programs available for error reporting include United States Pharmacopeia (USP)/Institute for Safe Medication Practices (ISMP) program called Medication Errors Reporting Program (MERP). Reports in this program can be done through the phone, email, website or postage paid forms. The web site is ISMP.org.

Another program is the FDA Medwatch Program. This program is not exclusive to medication errors but also for devices, food products, etc. Medwatch forms can be completed on the FDA website (FDA.gov) or by postage paid forms. Lastly,USP also has MedMARx which is an internet based reporting system that facilities can pay for which will deliver various tools to assist facilities in fixing errors that are occurring.

Focus Drug of the Month

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Since this newsletter will be published every other month two medications will be presented in this section.

**This issue will only focus on one drug.

Sonata® , Zaleplon

This medication is FDA approved for treating short-term insomnia. Insomnia is defined as difficulty falling or maintaining sleep, which interferes with daytime functioning.

The dosing for this medication is 10mg for adults. For elderly, the recommended dose is 5 mg.

Individuals who are taking this drug should be monitored for adverse reactions, number of times they wake up at night, time it takes the individual to fall asleep and, lastly, daytime functioning should be monitored.

Sonata® is a medication that basically is reserved for those individuals who have a hard time falling asleep where non-drug therapy has failed.

Medications for insomnia are a group of drugs that undoubtedly raise issues for health care professionals. Very often these medications are requested, abused and misunderstood by individuals who take them. This stems from misunderstandings about insomnia itself and the perception of the medications that are available.

In fact , these medications are not without risk. Sometimes insomnia is a sign of untreated conditions and therefore the use of these medications just masks another

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In both "wearing-off" and dyskinesias, modifying levodopa therapy is usually the first intervention. In dyskinesias, lowering the dose is attempted. In "wearing-off", the timing between levodopa doses is shortened. In some cases, moving to a longer acting levodopa product (Sinemet CR®) may also reduce the "wearing-off" effect.

Beyond adjusting levodopa, there are two additional groups of medications used to attack these motor complications. They are called direct-acting dopamine agonists and catechol-O-methyltransferase (COMT) inhibitors. Dopamine agonists include Parlodel®, Permax®, Mirapex® and Requip®. COMT inhibitors include Tasmar® and Comtan®.

In addition to these two groups of medications, there are other medications often prescribed for individuals with Parkinson's disease. They include selegiline, Artane®, Cogentin®, Inderal®, Remeron® and amantadine. The focus of this article will be to look at the dopamine agonists and the COMT inhibitors.

The term dopamine agonist can be intimidating. To help understand the term better, think of dopamine agonists as a levodopa "helper". How do these drugs help levodopa do its job better? First, dopamine agonists work for a longer period of time compared to levodopa. These drugs also have a lesser likelihood of causing dysinesias as compared to levodopa. The net effect of adding a dopamine agonist is that usually levopdopa doses can be lowered to alleviate dyskenisias. Since these drugs also last longer those individuals who experience "wearing-off" actually experience less "off" time.

The trouble with dopamine agonists however is side effects. Dopamine agonist side effects include psychosis, orthostatic hypotension, dyskinesias and nausea. Therefore individuals on these medications should be monitored for these side effects. Also, as with many medications, these medications should be started at low doses and titrated up very slowly.

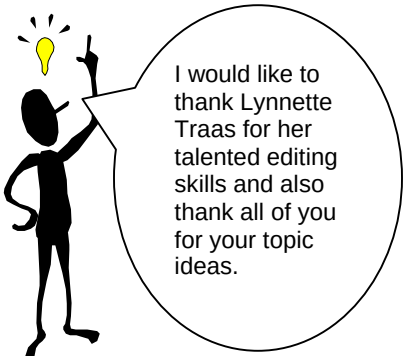
"COMT inhibitor" is another intimidating term. Thinking of COMT inhibitors as "scout snipers" helps illustrate the purpose of these problem. In other cases these medications do carry significant side effects.

It is for these reasons that upon presentation of insomnia complaints, a good assessment and education of the individual is critical. Very often assessments will determine that another medication the person is taking is causing the insomnia. Good examples of these include antidepressants like Prozac®. In these cases, changing the timing of that offending drug may eliminate the insomnia.

In other cases, illnesses like hyperthyroidism or untreated pain may be causing the insomnia. In these instances simple interventions to treat the pain or hyperthyroidism may eliminate the insomnia. Educating patients that treating the underlying condition will help their insomnia is extremely important.

Education and assessment lead to better treatment options and will help patients avoid chronic reliance on sleep-inducing medications.

If there are medications you would like featured here please send an email to Doug at engleda@dhfs.state.wi.us



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Did you know?

In section 'O' of the MDS, nutraceuticals like gingko biloba and St. John's wort should not be counted as medications under MDS item 01, Number of Medications.

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dispensed. Often this is called an expiration date, but the correct term for a medication that is dispensed by a pharmacist is "Beyond-Use Date."

One other item that may be of interest is that in August of 1999 USP added a revision in USP24/NF19 that addresses beyond-use dates for patient medication packages. In these types of containers where 2 or more medications may be contained in a series of containers (sometimes called medisets), the recommended beyond use dating should be no longer than 60 days. This requirement also states that "once a medication has been placed in a patient med pak with another solid dosage form, it may not be returned to stock, redistributed or resold if unused."

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medications. Remember, Parkinson's disease causes a decrease in dopamine. Dopamine that is produced or administered in the form of levodopa is broken down in our bodies by various enzymes. COMT snipers basically attack these enzymes so dopamine is not broken down. These drugs usually work best for those individuals experiencing "wearing-off" effects due to the fact that they increase the period of time levodopa works. These medications also carry significant side effects. Notably they can cause dyskinesias, psychosis, diarrhea and othorstatic hypotension. Tasmar® also has been associated with liver toxicity. For those reasons, Tasmar® should only be used after other medications have failed. In addition liver function tests are recommended at baseline and at regular intervals.

As you can see, as Parkinson's disease advances, the treatment options become a balancing act of treating the parkinsonism and decreasing the side effects of these medications. Detailed monitoring is extremely important to optimizing treatment, avoiding side effects and avoiding unnecessary drugs.

Consultant's Corner

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This section is basically a miscellaneous section that will show up each issue and will contain tidbits of information, most of which will come directly from your questions. If there is a topic you want more detailed information about, please drop me an email at engleda@dhfs.state.wi.us and I'll see what I can find.

What's the difference between a drug irregularity and an unnecessary drug? Occasionally those of you who work in nursing homes will ask this question. The simple answer is that in some circumstances there are no differences, it is just a different term used depending on the regulations that apply.

To explain further, a drug irregularity describes a problem or a potential problem with a medication. An irregularity occurs when the objective of the medication is not being achieved or when there is not a stated objective or indication for a medication. Drug irregularities are medication risks that pharmacists should be identifying when they perform a drug regimen review.

Some specific drug irregularities have been identified in the Health Care Financing Administration (HCFA) State Operations Manual (SOM). However, pharmacists are expected to abide by current practice standards. If there are irregularities occurring with medications that are not identified in the SOM, the pharmacist is still required to report them.

Now, what's the difference between an irregularity and an unnecessary drug? The easiest way to answer this is that in some instances drug irregularities can become unnecessary drugs. The SOM provides definitions and additional information about unnecessary drugs in nursing homes. The point here is that if the pharmacist fails to identify and communicate a medication risk, it is defined as an irregularity and the drug regimen review requirements for pharmacists in nursing homes apply. If an irregularity then meets the definition of an unnecessary drug those regulations could apply as well.

Let's look at an example. If a resident is on a high dose of antipsychotic medication without a dose reduction and the pharmacist fails to identify this fact, it may represent an irregularity. If the antipsychotic is in excessive dose that is not justified and there are potential negative outcomes, then this may also represent an unnecessary drug.

References are available upon request.